SUMMARY REPORT OF THE MEETING ON DEVELOPMENT OF A METALS ASSESSMENT FRAMEWORK

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NOTICE

The statements in this report reflect the views and opinions of the workshop experts. They do not represent analyses or positions of the Risk Assessment Forum or the U.S. Environmental Protection Agency (EPA).

This report was prepared by Eastern Research Group, Inc., an EPA contractor, as a general record of discussion held during the Meeting on Development of a Metals Assessment Framework (February 20, 2002). As EPA requested, this report captures the main points and highlights of the meeting. It is not a complete record of all details discussed, nor does it embellish, interpret, or enlarge upon matters that were incomplete or unclear.

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EXECUTIVE SUMMARY

EPA convened a one-day meeting on February 20, 2002 to gather stakeholder input for an Action Plan for the development of a Metals Assessment Framework. The meeting was held at the Holiday Inn Washington Capitol Hotel in Washington, D.C. Approximately 40 stakeholders representing industry and regulatory agencies attended the meeting. Five stakeholders presented comments.

The stakeholders agreed that the Metals Assessment Framework should be based on sound science, and that it should provide a basis for appropriately identifying the risks of metals to human health and the environment. The Framework should support EPA's principles and should be structured to mesh with similar EPA and international programs.

The stakeholders believed that the method of determining the hazard of a metal should be modified from the Persistence, Bioaccumulation, and Toxicity (PBT) approach developed for evaluating organics. Suggested alternative methods for evaluating metals toxicity included redefining "persistence" in metals to consider bioavailability, consideration of the nonintrinsic bioaccumulation property of metals, and consideration of speciation and bioavailability.

The stakeholders agreed that EPA should continue to solicit input from stakeholders and other interested parties in the development of the Framework. Further, the stakeholders agreed that the Science Advisory Board should review the Action Plan and the Framework and that EPA should solicit public comment during this review.

1. INTRODUCTION

1.1 Meeting Purpose

Since the promulgation of the Toxics Release Inventory (TRI) lead rulemaking, there has been considerable interest in the scientific assessments that the U.S. Environmental Protection Agency (EPA) conducts on metals and metals compounds. Based on discussions with stakeholders and concerns expressed formally by Congress, EPA recognizes the importance of developing a more comprehensive approach to metals assessments that could serve as the basis for future Agency actions. To this end, EPA is developing an Action Plan in coordination with Science Advisory Board consultation and review. To gather stakeholder input for the Action Plan, EPA convened a one-day meeting on February 20, 2002 at the Holiday Inn Washington Capitol Hotel in Washington, D.C. This meeting was announced in a Federal Register notice (FRL-7138-3) on February 6, 2002.

The purpose of the meeting was to collect input from stakeholders to help EPA formulate an Action Plan for developing a Metals Assessment Framework. Specifically, EPA solicited input on the following questions, which were listed in the Federal Register notice:

- What organizing principles should the Framework follow?
- What scientific issues should the Framework address?
- What methods and models should be considered for inclusion in the Framework?
- What specific steps should be taken to further involve the public and the scientific community in the development of the Framework?

Approximately 40 stakeholders representing both industry and regulatory agencies attended the meeting (see Appendix A).

1.2 Meeting Agenda

Appendix B presents the meeting agenda. EPA began the meeting with opening remarks and a presentation of the background and scope of the development of a Metals Assessment Framework. Then, EPA accepted questions from the audience regarding the background and scope. Next, three preregistered commenters gave presentations on the hazard assessment of metals, bioaccumulation of metals and metal compounds, and the development of a Framework for assessing metals and metals compounds. The presenters responded to questions from the audience about their presentations.

Then, two additional preregistered commenters gave presentations addressing EPA's specific questions from the Federal Register notice, the state of the science for PBT chemical

assessment, and the peer review procedures that EPA should implement in developing the Metals Assessment Framework. Two other preregistered commenters who were listed in the agenda did not speak. Finally, the audience was invited to ask further questions of the presenters; however, no questions were asked. The audience was invited to make comments; none were made. EPA concluded the meeting by thanking the participants.

1.3 Meeting Summary

This report summarizes the workshop presentations and discussions and is organized as follows:

- Section 2 summarizes EPA's opening presentation and remarks, including clarification questions and answers. Appendix C presents the slides used in the presentation.

- Section 3 summarizes the five presentations, including clarification questions and answers. Appendices D, E, F, and H present slides used in these presentations. Appendices G and I contain written comments submitted by two of the presenters.

- Section 4 summarizes EPA's concluding remarks.

2. SUMMARY OF OPENING PRESENTATION AND REMARKS

Vanessa Vu of EPA's Office of Research and Development opened the meeting and welcomed the commenters and observers. Dr. Vu began her presentation by providing an overview of the background for the development of the Framework. (See Appendix C for slides of Dr. Vu's presentation.)

After the 2001 TRI lead rule was promulgated, EPA deferred the rule's findings regarding the bioaccumulative properties of lead and lead compounds, and stated that it would solicit external review from the Science Advisory Board (SAB) before taking any further action. EPA tasked an ad hoc technical panel to develop a white paper to frame the issues and set the charge for the SAB regarding whether lead compounds are highly bioaccumulative. While this technical panel was underway, EPA determined that it was necessary to develop a comprehensive Metals Assessment Framework that could provide a basis for future actions for all metals and metals compounds. To develop this Framework, EPA is soliciting comment from other government agencies, stakeholders, and the scientific community at large. EPA believes that this and future scientific workshops will facilitate receiving comment from all interested parties, so that EPA can incorporate these comments and expert advice in the Action Plan and provide this input to the SAB.

Dr. Vu said EPA envisioned that the Action Plan will present the issues and elements of the Framework, and will outline the steps that are needed to address these issues. The Action Plan will require public participation and SAB input to properly address the stated issues.

The purpose of the February 20, 2002 Meeting on Development of a Metals Assessment Framework was to receive comments from stakeholders on the Framework, focusing on the following key issues: organizing principles to be used; scientific issues; methods, models, and approaches; and steps to include in the development of the Framework. EPA is proposing the following schedule for completing the Action Plan:

January 2002:	EPA began development of the Action Plan and formed the Science Policy Council Metals Action Plan Workgroup.
February 2002:	EPA held this first public meeting to solicit comment.
March 2002:	EPA will bring the draft Action Plan to the Science Policy Council for review.
May 2002:	EPA will publish the draft Action Plan.
June 2002:	SAB will review the draft Action Plan.

July 2002:	EPA will begin developing the Framework based on SAB review of the Action Plan.
March 2003:	SAB will review the Framework.
June 2003:	SAB will publish their review of the Framework.
December 2003:	EPA will publish the Framework.

Dr. Vu reiterated that EPA is committed to considering stakeholder comments and recommendations, and requested that commenters focus on the scientific issues and suggest approaches for the Framework. Dr. Vu then introduced Bill Wood, the Director of EPA's Risk Assessment Forum (RAF), co-chair of the Metals Action Plan Workgroup, and moderator for the meeting.

Dr. Wood explained the purpose of the Risk Assessment Forum. The Forum is a standing committee in EPA that is charged with developing risk assessment guidelines and fostering consistency within EPA in using these guidelines. The RAF was asked to put together an ad hoc technical panel to begin evaluating the issues associated with the TRI lead rule, persistence, and bioaccumulation. This effort will continue once the Framework is developed. The EPA Deputy Administrator feels that it is critical to develop a Framework for metals and metal compounds prior to continuing work on the TRI lead rule.

Questions and Answers

Audience participants questioned how long the public will be able to comment on the draft Action Plan. Dr. Vu explained that the draft Action Plan will not be available until May, and interested parties may submit input for up to 2 weeks before publication of the draft plan. Stakeholders may present comments on the draft Action Plan at the SAB meeting in June 2002.

An audience participant inquired if the Action Plan will encompass similar efforts underway in the national and international community, including the Organization for Economic Cooperation and Development (OECD) and the Harmonization of Classification of Substances. Dr. Vu responded that EPA will consider the ongoing efforts of other organizations in the development of the Action Plan.

An audience participant asked when the plenary discussion would occur during the meeting. Dr. Wood responded that stakeholders could comment after each presentation and during the "Public Comments" portion of the agenda.

3. COMMENTER PRESENTATIONS

Following EPA's opening remarks, Andrew Green, of the International Lead Zinc Research Organization presented the first of three linked presentations on metals assessment by the metals industry representatives. Dr. Green's presentation focused on metals hazard assessment and the issues present in the existing approaches. Kevin Brix of the Metals Ad Hoc Coalition followed with a presentation on the bioaccumulation properties of metals. William Adams from Kennecott Utah Copper completed the series with a presentation proposing principles and steps that should be considered for the Metals Assessment Framework. The audience then asked questions. Then, Neil King of Wilmer, Cutler, & Pickering provided comments on behalf of the Nickel Development Institute, the Nickel Producers Environmental Research Association, and Inco United States. Finally, Kevin Bromberg of the U.S. Small Business Administration discussed review procedures. This section summarizes these presentations and the brief question-and-answer session.

3.1 Andrew Green, International Lead Zinc Research Organization

Dr. Green introduced his presentation as an overview of hazard assessment for persistent, bioaccumulative, and toxic (PBT) substances. Slides of Dr. Green's presentation are provided in Appendix D. Dr. Green used the context of the PBT approach to identify the scientific issues, methods, and models that should be considered in developing the Framework.

EPA developed the PBT approach for organic chemicals in the 1970s. Based on this approach, tools were developed to prioritize PBT chemicals. During hazard assessment, EPA currently defines a PBT chemical as one that exhibits varying degrees of persistence, bioaccumulative properties, and toxicity.

Dr. Green noted that EPA is using the Waste Minimization Prioritization Tool as the current Framework for a hazard screening tool. This tool uses a scoring system for each of the three criteria (persistence, bioaccumulative properties, and toxicity). There are two issues to note in using this tool for metals assessment:

- First, this tool ranks the bioaccumulative and persistence criteria equally for both ecological and human endpoints.

- Second, this tool is specifically a hazard assessment tool, and the Metals Assessment Framework should provide a more comprehensive assessment of metals.

Dr. Green presented the current approach to evaluating the **persistence** of a chemical. A chemical is considered persistent in the environment if the half-life of the compound in soil, water, or sediments is longer than 2 months. Because metals are naturally present in the environment, they are, by nature, persistent, although they do not necessarily present a hazard.

Dr. Green proposed an alternative definition of persistence for metals and metal compounds: the property of a chemical whereby it remains in a bioavailable form in the environmental compartment. Other properties can also be used to evaluate persistence of metals, including the presence of the free metal ion, the tendency of partitioning to suspended solids, residence time in the water column before the metal becomes associated with sediments, the tendency for partitioning to sulfide in sediments, and whether the metal is easily re-suspended and re-entrained within the water column from the sediments.

Dr. Green presented three alternative sources of information that could be considered in developing a Metals Assessment Framework. Data were collected in Perch Lake, Canada to characterize the persistence of cobalt, iron, and zinc in the water column. The study demonstrated that the persistence of each metal varied widely. The Windermere Humic Acid model (WHAM) allows prediction of the concentration of free metal ion in water based upon water quality. Finally, the variation of the suspended solids partition coefficient (Kd) for various metals should also be considered in developing a Metals Assessment Framework.

Bioaccumulation is used as an indicator of chronic toxicity and of the potential for trophic transfer and biomagnification. A chemical is considered bioaccumulative if the bioaccumulation factor (BAF) or the bioconcentration factor (BCF) is greater than 1,000, or if the log octanol-water partition coefficient (K_{ow}) is greater than 3.0. Existing data and models can address the scientific issues associated with this criterion (see Section 3.2).

The current approach for evaluating **toxicity** was developed for organic chemicals and does not specifically address metals. Under this approach, a chemical is considered highly toxic if its toxicity values are less than 1 milligram per liter. Therefore, nearly all metals receive a high toxicity score based on the score for soluble metal salts, even though acute and chronic toxicity vary widely between metals and metal compounds. To adequately characterize metals toxicity, the following scientific issues should be considered in developing the Framework:

- There should be a distinction between metals and metal compounds.
- Speciation and transformation should be considered; soluble metal compounds should not be treated equally to insoluble metals.
- The scale of the Waste Minimization Prioritization Tool is not adequate to describe the variability of metals and metals compounds.
- Bioavailability is not considered. EPA has current methodologies in place that would more adequately characterize bioavailability, including the Biotic Ligand Model (BLM) for water and the Acid Volatile Sulfide - Simultaneously Extracted Metal (AVS-SEM) approach.

Dr. Green concluded his remarks by reiterating that the current approach that was developed for organic chemicals is inappropriate for use in metals assessment. In developing a Metals Assessment Framework, EPA should consider criteria that are specific to metals and incorporate the physicochemical properties of metals, and should consider existing data, information, concepts, and models that adequately characterize metals and metal compounds.

3.2 Kevin Brix, Metals Ad Hoc Coalition

Mr. Brix began his presentation by stating that the current approach for assessing bioaccumulation for metals has significant limitations. (See Appendix E for slides of Mr. Brix's presentation.) There is an inverse relationship between accumulation factors and exposure concentrations for metals, which is not reflected in the existing approach. He proposed an alternative approach to using accumulation factors.

The theoretical basis of the existing approach is based on organics and passive diffusion. Accumulation of organic substances is not expected to be concentration-dependent. The accumulation in an organism will be constant over a range of water concentrations.

Most metals, however, require active transport to facilitate uptake into organisms. Active transport mechanisms are rate-limited and, therefore, concentration-dependent. There is a range of water concentrations for metals over which an organism will maintain normal body burden. That is, the organism intake and excretion of the metal is maintained within normal levels. As the metal levels increase, the organism increases the metal excretion rate and decreases the intake rate. At high levels, the organism cannot maintain this regulatory mechanism and begins to exhibit toxic levels of the metal. For essential metals, when concentrations are low enough that the organism cannot uptake the metal at a rate to maintain normal body burden, then the organism will experience a deficiency and strive for a higher intake rate. Therefore, the BCF is inversely related, because the organism's intake rate increases as the concentration decreases and decreases as the concentration increases.

Mr. Brix presented data supporting this inverse BCF relationship. McGreer et al.[1] calculated a zero-slope relationship of the aquatic concentration of an organic (hexachlorobenzene) to the observed bioconcentration in five aquatic species. Therefore, the BCF is constant regardless of the organic aquatic concentration. Conversely, the relationship of the BCF to cadmium in water was observed to be inversely proportional for a wide range of organisms. The same inverse relationship was found for zinc BCFs. Biota-sediment accumulation factors (BSAFs) demonstrated the same inverse relationship for studies on

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[1]*McGreer, J.C., K.V. Brix, J.M. Skeaff, D.K. DeForest, S.I. Brigham, W.J. Adams and A.S. Green (2002). "The inverse relationship between bioconcentration factor and exposure concentration for metals: implications for hazard assessment of metals in the aquatic environment."* Environ. Toxicol. Chem. *Submitted.*

cadmium, copper, and zinc. Efroymson et al.[2] observed this same trend in observed plant-soil accumulation factors for arsenic, copper, lead, mercury, nickel, cadmium, and zinc.

As a side note, Mr. Brix noted that a report published a few years ago demonstrated a flat relationship for lead for bivalves. Since then, these data were reanalyzed to consider only steady-state conditions, and the inverse relationship is present under these conditions.

Mr. Brix presented an alternative to the fixed accumulation factor approach that evaluates the hazard potential of metals via bioaccumulation, based on dietary toxicity to consumer organisms. First, the wildlife dietary toxicity threshold is determined for a metal; this is a set threshold for an organism. Then, the threshold is related to the tissue concentration of the metal in prey organisms. Next, the concentration of metal in an aquatic environment that would produce that tissue concentration is determined. This approach was presented by Skorupa and Ohlendorf in 1991[3] and Ohlendorf and Santalo in 1994[4].

This regression approach was used to estimate the water concentration that results in the dietary threshold of an organism for six metal compounds. The wildlife dietary threshold is used with the inverse-BCF relationship to determine the water concentration that could cause effects via bioaccumulation.

Mr. Brix concluded his presentation noting that accumulation factors are not an intrinsic property for metals, and are clearly inversely related to water, sediment, and soil concentration. The regression approach is one that could be used to estimate threshold water concentration. The interpretation of this approach needs to be further developed.

Questions and Answers

An audience member stated that it may be appropriate to consider a range of dietary thresholds to account for age and health variability among organisms. Mr. Brix agreed that using a range or a conservative threshold is appropriate.

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[2]*Efroymson, R.A., B.E. Sample, and G.W. Suter (2001). "Uptake of inorganic chemicals from soil by plant leaves: regressions of field data."* Environ. Toxicol. Chem. ***20****(11):2561-2571.*

[3]*Skorupa, J.P. and H.M Ohlendorf (1991). Contaminants in drainage water and avian risk thresholds.* The Economics and Management of Water and Drainage in Agriculture*. A. Dinar and D. Zilberman. Boston, Kluwer Academics Publishers: pp. 346-368.*

[4]*Ohlendorf, H.M. and G.M. Santolo (1994). Kesterson Reservoir past, present, and future: an ecological risk assessment.* Selenium in the Environment. *W.T. Frankenberger and S. Benson. New York, Marcel Dekker, Inc.: pp. 69-117.*

An audience member inquired if the BCF data were analyzed using any other nonlinear methods. Mr. Brix stated that these data have only been analyzed using the log-linear approach, and it may be appropriate to analyze these data using other nonlinear transformations.

An audience member inquired why one would need to calculate the slope of the BCF if the water concentration and dietary threshold were known. Mr. Brix stated that this approach is intended to estimate the relationship between tissue concentration and threshold water concentration based on the dietary threshold.

3.3 William Adams, Kennecott Utah Copper

Dr. Adams began his presentation by noting that his remarks expand upon those offered in the preceding presentations. (See Appendix F for slides of Dr. Adam's presentation.) He first presented the issues associated with hazard assessment of metals, then discussed bioaccumulation of metals, and then discussed the overarching questions directed for this meeting by proposing a conceptual Framework.

Dr. Adams presented some organizing principles that could be considered in developing a Metals Assessment Framework. The Framework should:

- Support agency wide strategic goals and complement existing programs.
- Be based on sound science and models.
- Focus initially on hazard assessment as a screening mechanism.
- Utilize more detailed assessments for metals and metal compounds identified in the screening process, which might include lifecycle and uses of metals as well as release and exposure.

The Waste Minimization Prioritization Tool is a hazard identification tool, and should identify compounds that warrant further evaluation. The tool was developed based on organics, and it is thought to have a strong practical and theoretical basis. However, it is not particularly helpful for screening different metals because, for the most part, all metals receive the same score. Further, Dr. Adams indicated that there are no metals that have been identified that biomagnify, other than methylmercury, an organo-metallic substance. Because metals are naturally present in the environment, persistence as it is currently defined is not a useful metric. Therefore, this tool is not useful to prioritize metals.

Dr. Adams proposed an alternative metals assessment approach, and suggested that this three-tiered approach is used in other programs. The first tier is the hazard screening, which does not consider exposure or risk, but rather simply presents the hazard of the substance. The Canadian approach and the OECD for the classification of substances have a hazard screening at

the first tier. Dr. Adams suggested that perhaps in this first tier, the Metals Assessment Framework should also evaluate persistence and bioaccumulation of metals, in addition to multitoxicity scales. This would help to identify the metals that are of most concern in terms of hazard.

Whether these issues are resolved and included for a Tier 1 assessment or they are deferred to Tier 2, methodologies for determining the following items need to be developed for metals assessment:

- Persistence
- Bioavailability
- Bioaccumulation
- Toxicity
- Speciation

These items could be considered a tool box for making hazard determinations on metals.

Tier 2 of this proposed approach is the next step looking beyond the intrinsic properties of the metal using physicochemical property estimations. Tier 2 would incorporate product use patterns, products, lifecycle considerations, recycle rate, and production volume.

Tier 3 would occur when the preliminary assessments from Tiers 2 and 3 identify a potential problem with a product or a substance. It would be helpful if some criteria and guidelines were established that set protocols for when it is appropriate to move from one tier to another. Tier 3 would be a site-specific assessment that includes the detail of monitoring and modeling studies in addition to site-specific information. The Ecological Risk Assessment Framework is consistent with this proposed approach.

Dr. Adams believes that it would facilitate the Metals Assessment Framework to incorporate the existing EPA programs that involve metals. There are already designations for hazardous metals within the Agency. There are eleven metals listed as hazardous air pollutants, thirteen metals on the priority pollutant list, and there are eight metals listed on the RCRA hazardous metals list. However, these programs do not assess risk for the metals.

The second question posed in the Federal Register notice asks what scientific issues should the Framework address. Dr. Adams proposed that the following key issues are important to include in the development of the Framework:

- Valid approaches for assessing persistence.

- Alternative approaches for assessing bioaccumulation.
- The inclusion of the bioavailability property of the substance.
- Determination of what is considered significant bioaccumulation of metals in human beings.
- Differentiation between substances and elements.

The third question posed in the Federal Register notice asks what methods and models should be included in the Framework. Dr. Adams proposes that the bioaccumulation model presented by Kevin Brix be considered. Also, there are a number of existing speciation models that could be used to predict species of metals present in water and soils, such as the Windermere Humic Acid model. The Biotic Ligand Model (BLM) has been well developed for copper, reasonably developed for silver and is under development for cadmium, zinc, and other metals. The BLM addresses bioavailability and predicts toxicity in an aquatic environment. Another model under development within industry is the Unit World Model. This model is similar in concept to the MacKay Fugacity model for organic chemicals, which predicts the distribution of a chemical to water, soil, and air upon release in the environment. The Unit World Model will perform the same function for metals in the environment.

The fourth question posed in the Federal Register asks what steps should be taken to further involve the public and the scientific community in developing the Metals Assessment Framework. Dr. Adams believes that the Framework can be effectively laid out if there is continued dialogue between EPA and stakeholders; perhaps stakeholder groups could be established specifically tasked to work with EPA in this effort. Finally, the Pellston workshop will be held this summer and will focus on the science of bioaccumulation and persistence. This workshop is organized under the Society of Toxicology and Chemistry and is being developed in coordination with EPA and other organizations.

Questions and Answers

An audience member noted that the inverse relationship of accumulation factors to metals concentration is contrary to what was presented during the TRI lead proceedings, and that this relationship is now based on steady-state conditions, whereas previously it included all data. The participant inquired if this inverse relationship holds true for other metals. Mr. Brix responded that this relationship has been observed for the accumulation of all metals in bivalves. The reanalysis of the lead data is what triggered the analysis for other metals. Dr. Adams noted further that not all organics have accumulation factors independent of concentration, even though the organic theory is that BCF is independent.

An audience member inquired if the BAF and BCF for aluminum, copper, zinc, and iron could all have values exceeding 1,000 and 5,000 for all species and any water concentrations. Dr.

Adams explained that the BAF for those metals in a clean environment is above 1,000. The BCF is the water concentration divided by the tissue level for the organism, and it is derived in a laboratory and does not take diet into consideration. The BAF is calculated the same way, but considers diet and is usually derived from data collected in the field. BAF is usually greater than BCF.

An audience member requested that Dr. Adams elaborate on how speciation is incorporated into his approach. Dr. Adams explained that elemental metal is zerovalent and not ionic; therefore, it is not very soluble. Rather, the metal has to be transformed to an ionic metal species that has greater solubility. Typically, the metal oxide is the first metal compound that is formed, followed by more complex metal compounds. These metal compounds dissociate in water to provide free metal ions. Metals and metal compounds need to be distinguished from each other, because it may be only certain forms of the metal that are toxic. Speciation models, such as the BLM, account for these different metal forms and their bioavailability.

Bill Wood (EPA Risk Assessment Forum) asked how Dr. Adams would apply these principles to the hazard assessment Tier 1 approach. Dr. Adams proposed that the rate of transformation and dissolution should be considered, as it is considered by OECD. OECD is developing a system of classification to distinguish between highly toxic, toxic, and less toxic compounds. This system will need to distinguish between different metal compounds. Relatively insoluble metals have slow rates of dissolution, so it is important to measure the rate and extent of transformation (i.e., to determine if the compound can go into solution at a sufficient rate and extent to express its toxicity). These principles could be incorporated into a Tier 1 assessment.

Vanessa Vu noted that Dr. Adams referenced a few models for use in the Metals Assessment Framework, and asked him to comment on how these models could be applied in a screening level assessment or a higher level risk assessment. Dr. Adams answered that this issue may be a good topic for a group to discuss, given that some models are more developed than others. The Unit World Model does not yet exist; however, it would apply to the screening level. The models that measure sorption to suspended solids, DOC binding, etc. would be appropriate for Tier 1, although that subject may be under debate. The proposed accumulation model could be applied across all three assessment tiers. The BLM for speciation may be most appropriate for Tier 2 or 3.

3.4 Neil King, Wilmer, Cutler, & Pickering

Neil King made comments representing the Nickel Development Institute, the Nickel Producers Environmental Research Association, and Inco United States, Inc. Mr. King noted that the three previous presentations reflected much of the nickel industry's positions. Mr. King provided written comments to EPA, which are provided in Appendix G.

The Framework should provide a basis for identifying and prioritizing potentially unreasonable risks to human health and the environment that may be posed by some metals and

metals species. To that end, the Framework should be able to discriminate between the various metals, metal alloys, and other metal compounds (including different species of a particular metal) with respect to hazard and risk.

Mr. King noted some organizing principles that should be incorporated into the Framework. The Framework should be developed using sound science, and it should be flexible enough to allow for the incorporation of new methods and models as our understanding of metals' fate, transport, bioavailability, and toxicity increases over time. The Framework should recognize that "inherent toxicity" is not meaningful with respect to metals and metal compounds, because there are other factors that determine if the compound will become bioavailable under specific circumstances. It would be useful to structure the Framework using a tiered approach. The most generalized level would be a hazard evaluation, and higher tiers would include screening-level risk assessments and site-specific risk assessments. Finally, the Framework should be designed to serve as a predicate for establishing voluntary and regulatory initiatives to achieve significant risk reduction benefits in a cost-effective manner. For many metals, this will involve increasing the rate at which wastes and other secondary materials containing the metal are recycled.

Mr. King identified three broad scientific issues that should be addressed in the Framework:

1) The Framework has to distinguish between the persistence of metals as fundamental elements and "bioavailable persistence." This latter concept requires consideration of speciation, transformation, and bioavailability.

2) The Framework should recognize that bioaccumulation as it is applied to organic compounds is highly problematic as a criterion to evaluate potential hazard or risk in the case of metals. Bioaccumulation is not an inherent property of metals, nor is it an indicator of toxicity for metals. Moreover, virtually all metals do not biomagnify in the food chain.

3) In evaluating the toxicity of metals, the Framework must consider speciation, transformation, and bioavailability.

Mr. King then commented that EPA might use both formal and informal mechanisms to involve the public and scientific community in developing the Framework. Informal mechanisms could include Federal Register notices and an e-mail network to keep interested parties apprized of developments. At the same time, EPA should establish a more formalized consultation mechanism utilizing a group of scientifically knowledgeable stakeholders, as well as expert workshops. Mr. King noted that the January 2000 workshop was very helpful, and hopes that EPA will schedule similar workshops on this topic in the future. Mr. King emphasized that EPA should allow enough time for meaningful public comments when the draft Action Plan and draft

Framework are submitted for SAB review, and enough time to present public comment during the SAB meetings themselves.

Mr. King stated that the Framework should be developed for application to all metals and inorganic metal compounds, including lead. With that in mind, when the Framework is completed, EPA should apply it to lead as a reality check on the PBT characterization that was assigned to lead for the purposes of the TRI program.

Finally, Mr. King asked that state agencies be kept up-to-date regarding the development of EPA's Metals Assessment Framework. In the regard, he noted that when the draft PBT chemical list was published a couple of years ago, some state agencies began—prematurely—to design programs to regulate the chemicals on that list as PBT substances, even though EPA was not even close to deciding what chemicals should appear on the PBT list as finalized. Keeping state agencies more closely "in the loop" as the Framework is developed should help prevent premature actions of this sort in the future.

The audience was invited to ask questions; no questions were asked.

3.5 Kevin Bromberg, U.S. Small Business Administration, Office of Advocacy

Mr. Bromberg introduced himself and the Office of Advocacy within the U.S. Small Business Administration (SBA), stating that the function of the Office of Advocacy is to be the advocate for small business within the Federal Government. Mr. Bromberg described his background in science and law, and then opened his presentation with two key questions:

- What is the state of the science of PBTs and metals at EPA?
- What peer review procedures should EPA now conduct for the TRI lead rule?

Mr. Bromberg disclosed his agency's position on the TRI lead rule to provide a context for his comments. The SBA Office of Advocacy sent a letter to the Administrator on the TRI Rule stating their belief that there was no scientific basis for the rule, and urged the EPA to get SAB review. There has been a 13-month delay between the publication of the TRI Rule and the initiation of the SAB review, which reflects the combination of science and politics involved in this issue.

The state of the science now at EPA includes equal treatment of metals and organics. The 1999 PBT rule treats metals like organics because "under certain conditions, all metals can be bioavailable under some conditions." Therefore, the EPA asserted that it was appropriate to consider all metals under this scheme. The Agency did not address, however, bioaccumulation in

1999, which also is different for metals and organics. A 1998 OECD report[5] states that research into this issue should be approached with care, because metals are different in several ways from PBT organic chemicals. However, despite the OECD precaution and other international organization recognition that metals should be treated differently than organics, EPA continued the lead rule under the assumption that all metals are bioavailable under certain circumstances.

When the TRI interagency review occurred, Mr. Bromberg solicited U.S. government scientists to review this issue of bioavailability and bioaccumulation. These two scientists were on the Canadian working group studying this same issue. Margaret Cavinaugh, a well-respected inorganic scientist stated, "The criteria for organics do not provide a sound basis for discriminating benign and harmful substances." Jim Hickey from the U.S. Geological Survey stated, "The BAF approach should not be used for the assessment of metal compounds." These comments were forwarded to EPA, and yet the rule went forward with the same approach used for metals as for organics. Mr. Bromberg requested literature support for this decision from EPA, but none was provided. The peer review procedures in the December 2000 SPC handbook[6] were not followed. EPA indicated that the SAB would conduct its review after the rule was published.

The recently published Inorganic Working Group's report (December 2001)[7] noted that the approach to synthetic organics is not applicable to inorganics. Mr. Bromberg feels that these findings should be incorporated into the Framework.

EPA did not follow SAB peer review procedures for the TRI lead rule. Mr. Bromberg noted that the peer review process is well outlined in the SPC handbook, and EPA should simply follow these procedures. EPA has indicated that it will follow the handbook as a matter of procedure. There is a question as to when an independent peer review should occur versus an internal EPA review. Mr. Bromberg stated that, according to EPA procedures, an independent review should occur for significant rules.

The SAB enacted new procedures to supplement the handbook, and SBA commends that effort. EPA should be cognizant of these procedures, including the procedures for selecting the review panel, with full disclosure of the experts' qualifications and any conflict of interest. EPA

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[5]*OECD (1998). Harmonized integrated hazard classification system for human health and environmental effects of chemical substances. As endorsed by the 28th Joint Meeting of the Chemicals Committee and the Working Party on Chemicals in November 1998. OECD, Paris, France.*

[6]*ORD (December 2000). Peer Review, EPA Science Policy Council Handbook, 2nd edition, EPA100-B-00-0001.*

[7]*IWG Report to Environment Canada (December 2001). Categorization of Inorganic Substances on the Domestic Substances List (DSL): Findings and Recommendations from the Inorganic Working Group (IWG). IWG Secretariat, Environment Canada, Hull, Quebec.*

is beginning the SAB consultation process for the Action Plan, and EPA should also include a full SAB review for both the Metals Assessment Framework and the TRI lead rule.

Mr. Bromberg does not believe that the PBT method is applicable to metals assessment. Therefore, the PBT method is not appropriate for lead assessment. Further, BCF and BAF factors cannot be used for metals assessment, given the state of the science today. An alternative scheme could be used; previous commenters presented some possibilities.

Mr. Bromberg then discussed next steps. After EPA develops the Action Plan, the Agency should solicit public comment. The selection of the SAB panel should consider background, balance, and diversity. As part of the SAB review of the new Metals Assessment Framework, the SAB will also review the former methodology that underlies the TRI lead rule.

EPA has stated in the Federal Register notice for this meeting, "EPA will not reconsider past actions." Mr. Bromberg stated that this does not mean that EPA is not looking at the TRI lead rule. EPA is looking at the TRI rule and possibly refining it. Perhaps EPA intended to state that it does not intend to reconsider past actions. Mr. Bromberg believes that EPA will do what is appropriate at the appropriate time to develop this Framework and the TRI lead rule, if it finds that its approach lacked a scientific foundation. Slides for Mr. Bromberg's presentation are included in Appendix H and a summary of his presentation is provided in Appendix I.

The audience was invited to ask questions; no questions were asked.

4. CLOSING REMARKS

Vanessa Vu clarified that the SAB has three levels of review: consultation, advisory, and full review. The SAB will provide an advisory review of the Action Plan, and a full review of the Metals Assessment Framework.

Dr. Vu thanked the speakers for their presentations and comments. Dr. Wood also thanked the presenters. He noted that the schedule for developing the Framework is aggressive, and will therefore need good dialogue between EPA, the stakeholders, and the scientific community. The Action Plan will outline what some of these interactions will be. The comments received during this meeting offered constructive ideas that EPA will consider and discuss. The meeting notes will be available online, and EPA will announce when the SAB meeting will occur. Dr. Wood asked participants to provide information on candidates for the peer review panel to Don Barnes, who will be assembling this panel.